IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH HOLDINGS CORPORATION, WYETHY-AYERST LEDERLE LLC, and WYETH LLC,	)	
Plaintiffs and Counterclaim Defendants,	)	
v.	)	C.A. No.09-955 (LPS)
SANDOZ INC.,	)	
Defendant and Counterclaim Plaintiff.	)	

AMENDED AND SUPPLEMENTAL COMPLAINT

Plaintiffs Wyeth Holdings Corporation, Wyeth-Ayerst Lederle, LLC, and Wyeth LLC (collectively, "Wyeth") for their Amended and Supplemental Complaint herein, aver as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code.

JURISDICTION AND VENUE

2. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

3. This court has personal jurisdiction over the defendant Sandoz Inc. ("Sandoz") because, *inter alia*, Sandoz has purposefully availed itself of the rights and benefits of Delaware law. Upon information and belief, Sandoz has continuous and systematic business contacts with the State of Delaware. Among other things, Sandoz previously admitted that it is licensed with the Delaware Board of Pharmacy as a "Distributor/Manufacturer CSR" and

"Pharmacy-Wholesale."[1] Additionally, Sandoz has previously stated it will not oppose personal jurisdiction in this Judicial District for this action, and has not opposed personal jurisdiction for this action.

4. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

THE PARTIES

5. Plaintiff Wyeth Holdings Corporation is a corporation organized and existing under the laws of the State of Maine, having its principal place of business at 5 Giralda Farms, Madison, NJ 07940. Wyeth Holdings Corporation is the owner of United States Patent No. RE40,183 (the '183 reissue patent") identified in paragraph 9 below.

6. Plaintiff Wyeth-Ayerst Lederle LLC is a limited liability company of Puerto Rico, having its principal place of business at 65th Infantry Avenue, Kilometer 9.7, Carolina, Puerto Rico 00987. Wyeth-Ayerst Lederle LLC is the exclusive licensee of the '183 reissue patent identified in paragraph 9 below.

7. Plaintiff Wyeth LLC is a is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 5 Giralda Farms, Madison, NJ 07940. Wyeth LLC is the owner of United States Patent No. 7,879,828 ("the '828 patent") identified in paragraph 11 below.

8. Sandoz has previously admitted that it is a corporation organized under the laws of Colorado, having a principal place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540. Upon information and belief, Sandoz does business in the state of Delaware.

[1] References to prior consent and prior admissions by Sandoz herein are based on Sandoz's February 3, 2010 Answer to Complaint (D.I. 9).

THE PATENTS-IN-SUIT

9. Wyeth Holdings Corporation is the lawful owner of all right, title, and interest in and to the following '183 reissue patent, including all right to sue and to recover for past infringement thereof, which patent is listed in the U.S. Food and Drug Administration ("FDA") "Orange Book" (*Approved Products With Therapeutic Equivalence Evaluation*) as covering the antibacterial medication TYGACIL®:

A. United States Patent No. RE40,183, entitled "7-SUBSTITUTED-9-SUBSTITUTED AMINO-6-DEMETHYL-6-DEOXYTETRACYCLINES", a copy of which is attached hereto as Exhibit A, which was duly and legally issued on March 25, 2008, naming Joseph J. Halavka, Phaik-Eng Sum, Yakov Gluzman, Ving J. Lee and Adma A. Ross as the inventors.

10. Wyeth-Ayerst Lederle LLC is the exclusive licensee of the '183 reissue patent. It markets and sells TYGACIL® in the United States.

11. Wyeth LLC is the lawful owner of all right, title, and interest in and to the following '828 patent, including all right to sue and to recover for past infringement thereof, which patent is listed in the FDA Orange Book as covering the antibacterial medication TYGACIL®:

A. United States Patent No. 7,879,828, entitled "TIGECYCLINE COMPOSITIONS AND METHOD OF PREPARATION", a copy of which is attached hereto as Exhibit B, which was duly and legally issued on February 1, 2011, naming Mahdi B. Fawzi, Tianmin Zhu and Syed M. Shah as the inventors.

SANDOZ'S ANDA FOR TIGECYCLINE INJECTABLE IV, 50 mg/vial
AND INFRINGEMENT OF THE '183 PATENT

12. Sandoz has previously admitted that it submitted Abbreviated New Drug Application ("ANDA") No. 91-620 to the FDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), in order to obtain approval to engage in the commercial manufacture, use, or sale of Tigecycline Injectable IV 50mg/vial before the expiration date of the '183 reissue patent. Upon information and belief, Sandoz's Tigecycline Injectable IV 50mg/vial is a generic version of TYGACIL®.

13. Sandoz has previously admitted that its proposed tigecycline product is bioequivalent to TYGACIL® and has the same active ingredient, route of administration, dosage form, and strength as TYGACIL®. Sandoz has also admitted that it is seeking approval for the same indications for which TYGACIL® is currently approved. Upon information and belief, Sandoz's generic tigecycline has the same excipients as TYGACIL® and has the same, or substantially the same proposed labeling as TYGACIL®.

14. Sandoz has previously admitted that it sent a letter dated October 30, 2009 addressed to Wyeth Holdings Corporation and third-party Wyeth Pharmaceuticals Inc., that included a "Notice of Certification Under 21 U.S.C. § 355(j)(2)(B) (§ 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act) and 21 C.F.R. § 314.95" ("the '183 reissue Notice Letter") with respect to the '183 reissue patent. The '183 reissue Notice Letter does not provide any valid basis for concluding that the '183 reissue patent is invalid and/or not infringed. Sandoz has previously admitted that Wyeth Holdings Corporation received the '183 reissue Notice Letter on November 2, 2009.

15. Sandoz has stipulated that the submission of ANDA No. 91-620 was an act of infringement of one or more claims of the '183 reissue patent under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A). (D.I. 40.)

16. Sandoz's generic tigecycline is the subject of one or more claims of the '183 reissue patent. Specifically, Sandoz has stipulated that its generic tigecycline is covered by claims 1, 2, 97 and 99-103 of the '183 reissue patent. (D.I. 40.)

17. Upon information and belief, Sandoz's manufacture, use, sale, and/or offer for sale of generic tigecycline will infringe, contribute to the infringement of, and induce infringement of one or more claims of the '183 reissue patent. Sandoz has previously admitted it was aware of the existence of the '183 reissue patent when Sandoz submitted ANDA No. 91-620 to the FDA. Upon information and belief, Sandoz had the specific intent to induce direct infringement of one or more claims of the '183 reissue patent by health care professionals and patients.

18. Upon information and belief, Sandoz has been aware of the existence of the '183 reissue patent, but nevertheless has infringed one or more claims of this patent in disregard of Plaintiffs' lawful rights under this patent, thus rendering this case "exceptional," as that term is set forth in 35 U.S.C. § 285.

19. The acts of infringement by Sandoz set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law and will continue unless enjoined by this Court.

SANDOZ'S ANDA FOR TIGECYCLINE INJECTABLE IV, 50 mg/vial AND INFRINGEMENT OF THE '828 PATENT

20. Wyeth refers to and incorporates herein the allegations of Paragraphs 1-19 above.

21. In a letter dated July 29, 2011 addressed to Wyeth LLC, third-parties Pfizer Inc. and Pfizer Pharmaceuticals, Inc., and counsel for Plaintiffs, Sandoz sent a "Notice of Certification Under 21 U.S.C. § 355(j)(2)(B) (§ 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act) and 21 C.F.R. § 314.95" ("the '828 Notice Letter") with respect to the '828 patent. The Notice Letter does not provide any valid basis for concluding that the '828 patent is invalid and/or not infringed. Wyeth LLC received the '828 Notice Letter on August 1, 2011.

22. Sandoz continues to pursue its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of its generic tigecycline before the expiration of the '828 patent.

23. Sandoz's continued efforts to pursue its ANDA to obtain approval to engage in the commercial manufacture, sale, offer for sale, and/or importation of its generic tigecycline before the expiration of the '828 patent is an act of infringement of one or more claims of the '828 patent under the United States Patent Laws, 35 U.S.C. § 271(e)(2)(A). Sandoz has stipulated that the submission of ANDA No. 91-620 was an act of infringement under 35 U.S.C. section 271(e)(2). (D.I. 40.)

24. Sandoz's generic tigecycline is the subject of one or more claims of the '828 patent. Specifically, Sandoz has stipulated that its generic tigecycline is covered by claims 1-4, 6-8, 10-12, 14, 16-18, 20, and 22-23 of the '828 patent. (D.I. 40.)

25. Upon information and belief, Sandoz's manufacture, use, sale, offer for sale, and/or importation of its generic tigecycline will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '828 patent.

26. Upon information and belief, Sandoz has been aware of the applications that led to the '828 patent and of the existence of the '828 patent once it issued, and has no

reasonable basis for believing that Sandoz's generic tigecycline will not infringe one or more claims of the '828 patent. This infringement by Sandoz will be willful and deliberate and in disregard of Wyeth's lawful rights under the '828 patent, thus rendering this case "exceptional", as that term is set forth in 35 U.S.C. § 285.

27. The acts of infringement by Sandoz set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law and will continue unless preliminarily and permanently enjoined by this Court.

RELIEF

WHEREFORE, Wyeth Holdings Corporation, Wyeth-Ayerst Lederle LLC, and Wyeth LLC pray for judgment against Sandoz as follows:

A. Adjudging that Sandoz has infringed one or more claims of the '183 reissue patent, and that the sale, offer for sale, and/or manufacture by the defendant of its generic tigecycline, would infringe, induce infringement of, and/or contribute to infringement of one or more claims of the '183 reissue patent;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Sandoz's ANDA No. 91-620, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date which is not earlier than the last date of expiration of the '183 reissue patent or '828 patent plus any additional periods of exclusivity;

C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Fed. R. Civ. P. 65, Sandoz, its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors or assigns, from any commercial manufacture, use, offer to sell or sale within the United States, or importation into

the United States, of any drug product that infringes one or more claims of the '183 reissue patent;

D. Adjudging that Sandoz's generic tigecycline and its use will infringe one or more claims of the '828 patent and that the sale, offer for sale, and/or manufacture by the defendant of its generic tigecycline will infringe, induce infringement of, and/or contribute to infringement of one or more claims of the '828 patent.

E. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Fed. R. Civ. P. 65, Sandoz, its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors or assigns, from any commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of any drug product that infringes one or more claims of the '828 patent

F. Declaring this an exceptional case and awarding Wyeth Holdings Corporation, Wyeth-Ayerst Lederle LLC, and Wyeth LLC their attorney fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

G. Awarding Wyeth Holdings Corporation, Wyeth-Ayerst Lederle LLC, and Wyeth LLC such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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